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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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RATNERPRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			EXAMINER WOO, JULLAN W	
			ART UNIT 3773	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/692,886

## Applicant(s)

GOICOECHEA ET AL.

## Examiner

Julian W. Woo

## Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 68, 70-81, 84, 93-112 and 129-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68, 70-81, 84, 93-112 and 129-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The disclosure is objected to because of an informality, which can be corrected as follows: In the specification and in claim 132, "angeological" should be replaced by --angiological--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 68, 71-81, 93-112, and 129-133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to base claim 68, a "skirt" is not recited or described in the specification. With respect to base claims 71 and 109, a graft body "circumferentially reinforced at locations along its length" or "circumferentially reinforced" is not described. Also with respect to claim 73, "sutures" are not mentioned as being used to attach "reinforcement wires"--also not specifically described in the specification--to a graft body (i.e., wires functioning as "reinforcement" are not described). Also with respect to claim 81, the term "crests" is not applied and described in the specification. With respect to base claims 93 and 107-109,

the specification does not describe "inlet" ends or "outlet" ends. Also, with respect to claims 111, the specification does not describe a graft with a "closed sinusoidal shape." Also with respect to claims 105 and 106, a "skirt portion" and its length are not described in the specification. Also with respect to claims 129 and 130, the specification does not describe first and second graft bodies and a metal wire structure having differing radiopacity or "radiographic indicia" or a "composite radiographic image" for indicating the "rotational orientation" of at least one of the first and second graft bodies and a metal wire structure in a body lumen.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 68, 70, 84, 93-96, 98-102, 104, 105, 107-110, 112, and 129-132 are rejected under 35 U.S.C. 102(e) as being anticipated by Barone et al. (5,360,443). Barone et al. disclose, at least in figures 7-9 and 11 and in col. 5, line 40 to col. 7, line 19; and col. 9, lines 19-51; a prosthesis or graft including a first graft (160), primary graft body, a bifurcated stent (160), or first graft body having a proximal portion or first graft body inlet end (at 166) and first and second distal portions (191), the proximal portion

defining a lumen and adapted to be in juxtaposition with a bifurcation in a blood vessel, where the first and second distal portions define lumens adapted to allow blood flow into respective first and second branched blood vessels; and a second graft (192), a supplemental graft body, or second graft body defining a lumen and adapted to intravascularly inserted into a lumen of the first graft; where the first distal portion has a downstream end forming a skirt (distal portion of 191); where the second graft body has a second graft body inlet end and a second graft body outlet end, the second graft body inlet end being attachable in an overlapping relationship with the first graft body outlet end (between 191 and 192), where the first and second graft bodies are reinforced by a metal wire structure (166, 192) sutured to a graft body (with sutures 170), where the first graft body is made of thin, biocompatible PTFE, where the wire structure is disposed at least in part on an outside surface of a graft body (proximal of 168), where the wire structure is disposed substantially on an inside surface of the first graft body (at 168), where the wire is X-ray detectable, where the second graft body is substantially cylindrical, where the wire structure comprises at least one wireform or a plurality of wireforms, where a portion (proximal) of the first graft body and the metal wire structure inherently has different radiopacity or radiographic indicia than another portion (e.g., a medial portion combined with PTFE), and where the graft is deployed with a system including first and second introducers (201).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 71, 73-75, 77-81, 106, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al. (5,360,443) in view of Wallsten (4,655,771).

Barone et al. disclose the invention substantially as claimed. Barone et al disclose a primary graft body and a supplemental graft body each circumferentially reinforced at locations along its length by a plurality of spaced apart portions of a tube and attached to the tube with sutures, where one of the portions of the tube extend beyond one end of the primary graft body. However, Barone et al. do not disclose that the graft bodies are reinforced by a plurality of spaced apart wires, where at least one of the wires has a different amplitude than the next adjacent wire or where at least one wireform has a closed sinusoidal shape. Barone et al. also do not disclose that the skirt portion is about 18 mm in length. Wallsten teaches, at least in figures 1a and 9 and in col. 2, lines 44-56; a prosthesis with a plurality of reinforcement wires formed as a tube, where wires are spaced apart and form a closed sinusoidal space. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of

Wallsten, to apply a plurality of reinforcement wires to the graft of Barone et al. Such wires would allow the graft to be more flexible for its deployment through a blood vessel, and they would allow secure fixation of the graft to the wall of the blood vessel. Moreover, it would have been a matter of obvious design choice to configure the wires, so that at least one of the wires has a different amplitude than the next adjacent wire. The choice would be dependent upon the desired length and flexibility for the graft. Also, it would have been a matter of design choice to size the skirt as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

***Response to Amendment***

8. Applicant's arguments filed on December 15, 2008 have been fully considered but they are not persuasive.

With respect to arguments regarding the rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph, and regarding the Applicant's use of the term "skirt" or "skirt portion": The Examiner respectfully disagrees with the Applicant's contention that one of ordinary skill in the art would recognize that "frustoconical part 78" of the present invention is a "skirt" or "skirt portion." That is, a "skirt" or "skirt portion" can have various definitions within and outside of the art, and a wireform, "frustoconical" element is not a generally-accepted meaning for a "skirt" or "skirt portion." Within the art, for example, Goldberg (3,818,511) teaches a prosthesis with a radially-divergent conical, fabric "skirt;" and Fabiani et al. (6,589,277) teach a prosthesis with a tubular, fabric "skirt." The ENCARTA

World English Dictionary defines "skirt" to include a "garment that hangs from waist," a "cut of beef," or a "flap on saddle." Applicant is reminded that he or she is allowed to use his or her own terms for elements of the invention as long as they are applied and defined in the specification. In other words, the Applicant is allowed to be his or her own lexicographer as long as term definitions are in the description. Applicant did not apply and define the term, "skirt" or "skirt portion," in the description.

Similarly for the term "crests," Applicant did not apply and define this term in the description. Like "skirt," "crests" has various definitions within and outside of the art. Frantzen (5,843,175), for example, teaches a prosthesis with "crests" at its mid-regions, not just at its ends. The ENCARTA World English Dictionary defines "crest" to include a "top of curve or slope," or a "tuft on animal's head," or a "helmet ornament." In short, "crests" does not have a generally-accepted meaning of reinforcement wires extending beyond an end of a graft, as set forth by the Applicant.

Regarding arguments about the Applicant's use of "circumferentially reinforced at locations along its length" and "circumferentially reinforced" under 35 U.S.C. 112, 1st paragraph: The figures of embodiments of the invention, as pointed out by the Applicant, do not indicate that the metal wire structure reinforces a graft body. That is, how can one of ordinary skill in the art glean such specific information regarding a mechanical action (reinforcement) of the metal wires from the figures? From the figures, one could guess that the graft body is reinforcing the metal wire structure or the metal wire structure may not be reinforcing the graft body at all. The specification mentions the assembly of a "wire skeleton" and a "fabric graft layer," but does not



describe the degree or specific locations of reinforcement of the graft layer by the wire, much less circumferential reinforcement.

Regarding the Applicant's use of the term "reinforcement wires" under 35 U.S.C. 112, 1st paragraph: First of all, the Examiner agrees with the Applicant that the specification discloses the attachment of a graft body to wires via sutures. However, the description does not specify "reinforcement wires" or wires for reinforcement—a specific mechanical action. As mentioned above, neither the description nor the figures indicate what elements of the invention are performing the function of "reinforcement."

Regarding the Applicant's use of the terms "inlet" and "outlet" ends under 35 U.S.C. 112, 1<sup>st</sup> paragraph: The Examiner respectfully disagrees with the Applicant that a graft body "must have an inlet end and an outlet end." One of ordinary skill would understand that a graft body may have ends, but to specify that one end is an "inlet" and another end is an "outlet" is a limitation not described in the specification. Such a description would be germane for understanding the configuration and orientation of the invention as claimed, yet the specification does not provide the information.

Regarding the Applicant's use of the term "sinusoidal" in the phrase "closed sinusoidal shape" under 35 U.S.C. 112, 1st paragraph: The Examiner contends that "sinusoidal," as applied in the claims, is not synonymous with the term "sinuous" as applied in the specification. The ENCARTA World English Dictionary defines "sinusoidal" to include "same as sine curve," i.e., "a graph of a sine equation;" while "sinuous" is defined as "winding or serpentine: full of bends and curves." That is, "sinusoidal," even a "closed sinusoidal shape," in the claim, describes a specific curve,

and it is a term that is not supported by a generally-described, "sinuous" or winding curve in the specification.

Regarding arguments regarding the "differing radiopacity" of the graft bodies under 35 U.S.C. 112, 1st paragraph: The Examiner respectfully disagrees with the Applicant that the specification provides support for the claim limitation regarding the "differing radiopacity." The specification's mere mention of a "platinum wire twisted around an apex of the prosthesis" does not lead one of ordinary skill in the art to the understanding that entire first and/or second graft bodies and metal wire structure have differing radiopacity.

With respect to arguments regarding the rejection under 35 U.S.C. 102 and based on Barone et al. Barone et al. indeed discloses, *inter alia*, "a second graft ...adapted to be intravascularly inserted into a lumen of said first graft." That is, the second graft and the first graft are both disclosed to be intravascularly positioned, while the second graft is already "inserted" (note the past tense of the verb) into the first graft. The claim does not require the action of inserting a second graft into the first graft outside a patient's body, nor does the claim require both grafts to be within a patient's body during the joining of the grafts. Applicant is reminded that limitations in the specification not included in the claim may not be relied upon to impart patentability to an otherwise unpatentable claim. In *re* Lundberg, 113 USPQ 530 (CCPA 1957). However, assuming *arguendo* that the second graft must be "adapted to be intravascularly inserted" into the first graft, while the grafts are within a patient's body: Applicant is also reminded that the recitation that an element is "adapted to" perform a

function only requires the ability to so perform. In re Hutchison, 69 USPQ 138. That is, both grafts of Barone et al. have the abilities to traverse and to be joined intravascularly. Moreover, patentable weight indeed is given to a limitation reciting the “adapted to” language only as far as a claimed element has the ability or capability to perform the recited function.

Regarding arguments regarding the “different radiopacity” of the graft bodies: The Examiner indeed provided extrinsic evidence that the graft bodies have differing radiopacity. That is, as mentioned in the rejection, a portion of the first graft body and the metal wire structure includes a PTFE tube, while the second graft body (e.g., 166 or 192) has a different configuration (i.e., a materially different, metal wire structure with a different size and shape from the first graft body). These differences would inherently lead to radiographic indicia or cues that would allow positioning of the graft bodies. Moreover, Barone et al. disclose, in col. 8, line 67 to col. 9, line 11, the positioning of graft bodies through the use of radiographic imaging, where clearly, differences in the graft bodies, and hence their radiographic images, allow proper positioning of the graft bodies at an aneurysm.

Regarding arguments regarding the rejection of claims 131 and 132, specifically: The Examiner indeed addressed Applicant’s arguments in the Office action of July 31, 2008. The Examiner indeed pointed out that Barone discloses first and second introducers, i.e., elements 201. With respect to claim 132, element 160 is a bifurcated stent member defining two lumens, while elements 192 are first and second graft

bodies. As shown in at least figures 7 and 8, elements 191, parts of element 160, define two passageways or lumens.

Regarding arguments regarding the rejection of claims 71, 73-75, 77-81, and 111 under 35 U.S.C. 103(a): The Examiner indeed addressed Applicant's arguments in the Office action of July 31, 2008:: Again, as shown above, Barone discloses the invention substantially as claimed, where a supplemental graft body is shown to be "dockable to said primary graft body while inside of a vessel" (i.e., the graft bodies are shown to be already docked while inside of a vessel--thus showing the ability for docking as claimed) or a second graft body is "attachable in an overlapping relationship" with a first graft body "while inside of a vessel" (i.e., the graft bodies are shown to be already attached in an overlapping relationship while inside a vessel--thus showing the ability for attachment as claimed). Wallsten was only applied for its teaching regarding wireform structures in an art analogous to Barone and the Applicant's invention.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

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